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COMPARISON OF EFFICACY OF IRON SUCROSE VS IRON POLYMALTOSE COMPLEX IN THE TREATMENT OF IRON DEFICIENCY ANEMIA IN CHILDREN

Original Research

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ABSTRACT

Background: Iron deficiency anemia (IDA) is the most common nutritional anemia affecting children globally and contributes significantly to morbidity and developmental delays. While iron sucrose has been extensively studied in adult populations, especially in pregnancy, limited data exists comparing its efficacy with iron polymaltose complex in pediatric patients. Given the importance of effective and well-tolerated treatment options for children, this study aimed to provide clinical evidence to guide iron replacement therapy in pediatric IDA.

Objective: To compare the efficacy of iron polymaltose complex versus intravenous iron sucrose in increasing hemoglobin levels in children diagnosed with iron deficiency anemia.

Methods: This randomized controlled trial was conducted in the Department of Pediatrics, Khyber Teaching Hospital, Peshawar, from October 11, 2024, to April 11, 2025. A total of 110 children aged 6 months to 5 years with confirmed IDA were randomized into two treatment groups. Group A received intravenous iron sucrose (5 mg/kg/day), and Group B received oral iron polymaltose complex (6 mg/kg/day) for eight weeks. Hemoglobin levels were measured at baseline and after treatment to assess efficacy, defined as an increase of ≥2 g/dl. Data were analyzed using SPSS 23 with $p \leq 0.05$ considered statistically significant.

Results: The mean age was 3.11 ± 1.37 years in the sucrose group and 3.73 ± 1.46 years in the polymaltose group. Male participants constituted 48.5% in the sucrose group and 51.5% in the polymaltose group. Efficacy was achieved in 38 patients (57.6%) treated with sucrose and 28 patients (42.4%) treated with polymaltose ($p = 0.052$). Mean hemoglobin increase was 2.25 g/dl in the sucrose group and 1.63 g/dl in the polymaltose group ($p = 0.011$).

Conclusion: Both iron sucrose and polymaltose are viable treatments for pediatric IDA. Although iron sucrose demonstrated a greater mean increase in hemoglobin, the difference in overall efficacy was not statistically significant. Treatment choice should consider individual patient factors including tolerance, adherence, and accessibility.

Keywords: Child, Hematinics, Iron Deficiency Anemia, Iron Polymaltose Complex, Iron Sucrose, Pediatric, Treatment Outcome.

INTRODUCTION

Iron deficiency anemia (IDA) remains the most widespread micronutrient deficiency globally, affecting approximately 33% of the world's population and constituting the leading cause of anemia (1). According to the World Health Organization, between 30% to 40% of individuals worldwide are anemic, and nearly half of these cases are attributable to IDA (2). This condition is particularly concerning in pediatric populations, with a high prevalence observed in children aged 4 to 23 months. In this age group, about 30% of those diagnosed with iron deficiency also exhibit anemia (3). While developed nations have seen a decline in the overall incidence of IDA, the condition persists as a major contributor to childhood anemia. In contrast, children in developing regions continue to experience high rates of iron deficiency, making it a pressing public health concern. IDA not only compromises hematological health but also poses significant risks to neurological development. There is compelling evidence that links iron deficiency in early childhood with delayed cognitive maturation and potentially irreversible impacts on brain function (4). Timely intervention is therefore critical, with iron supplementation serving as the cornerstone of treatment. However, oral iron preparations, including ferrous sulfate and ferrous gluconate, though commonly prescribed due to their high intestinal absorption rates (10–15%), are often associated with gastrointestinal side effects such as nausea, vomiting, and dyspepsia, leading to poor compliance in pediatric populations (5,6).

Among newer formulations, the iron polymaltose complex (IPC) has gained popularity due to its better tolerability profile. Nevertheless, data on its comparative efficacy remain sparse and inconsistent, particularly in pediatric settings (7). Studies have shown improvement in hemoglobin levels from 9.5 ± 1.10 g/dl to 11.7 ± 0.8 g/dl following oral IPC treatment (8). In contrast, intravenous iron sucrose therapy has demonstrated a more pronounced increase in hemoglobin levels, rising from 6.95 ± 0.72 g/dl to 12.10 ± 0.69 g/dl in children (9). Despite the clinical use of both formulations in pediatric practice, no randomized clinical trials have directly compared their efficacy in raising hemoglobin levels in children with IDA. Most existing studies either focus on adults, particularly pregnant women, or compare iron sucrose with other formulations such as ferrous sulfate. This presents a significant knowledge gap regarding optimal pediatric iron replacement therapy. Thus, the present study was designed to compare the efficacy of oral iron polymaltose complex versus intravenous iron sucrose in terms of mean hemoglobin improvement in children with IDA, aiming to identify the more effective and better-tolerated therapeutic option for this vulnerable population.

METHODS

This randomized controlled trial was conducted at the Department of Pediatrics, Khyber Teaching Hospital (KTH), Peshawar, over a six-month period from October 11, 2024, to April 11, 2025. The study population included children aged between 6 months and 5 years who were clinically diagnosed with iron deficiency anemia (IDA). Inclusion criteria required children to present with pallor and symptoms of easy fatigability, and confirmation of IDA was based on laboratory findings indicating a hemoglobin level of less than 10 g/dl along with serum ferritin levels below 7 ng/ml. Children with congenital aplastic anemia, recent blood transfusion within the past month, gastrointestinal bleeding, or known malabsorptive disorders were excluded to ensure a homogenous study cohort. The primary objective was to compare the efficacy of intravenous iron sucrose and oral iron polymaltose complex in improving hemoglobin levels. Efficacy was operationally defined as an increase in hemoglobin of at least 2 g/dl from baseline after 8 weeks of treatment. The hypothesis posited greater efficacy for iron sucrose over iron polymaltose complex in the pediatric management of IDA. A total sample size of 110 participants (55 per group) was calculated using OpenEpi software, assuming a 95% confidence interval, 80% power, and referencing post-treatment hemoglobin means and standard deviations reported in previous studies for both treatment groups (9,10). A non-probability consecutive sampling technique was employed to enroll eligible participants. After obtaining written informed consent from parents or legal guardians, baseline sociodemographic and clinical information was recorded for each child. Venous blood (5 cc) was drawn under aseptic conditions, with 2 cc allocated for complete blood count and 3 cc for serum ferritin estimation, and samples were analyzed by the hospital's hematology laboratory. Prior to treatment initiation, all participants underwent deworming as a standardized protocol to eliminate potential confounding factors.

Participants were randomly allocated into two treatment arms using computer-generated block randomization. Group A received intravenous iron sucrose at a dosage of 5 mg of elemental iron (Fe+++) per kilogram of body weight per day. The total required dose

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was calculated and divided over multiple sessions administered thrice weekly. The solution was diluted to a concentration of 1 mg Fe+++ per 1 ml of 0.9% sodium chloride and infused at a controlled rate of 1–1.3 ml/minute. Group B was administered oral iron polymaltose complex at a dosage of 6 mg/kg/day of elemental iron, given daily over a duration of eight weeks. Both groups were evaluated post-treatment to measure changes in hemoglobin concentration, and data were documented in a predesigned study proforma. Statistical analysis was performed using SPSS version 23. Descriptive statistics such as means and standard deviations were calculated for continuous variables including age and hemoglobin levels, while categorical variables like gender, vaccination status, residence, maternal education, and treatment efficacy were expressed as frequencies and percentages. The chi-square test was applied to compare efficacy between groups, while Fisher's exact test was used where cell frequencies were ≤5. Independent sample t-tests were used to compare mean post-treatment hemoglobin levels across the two groups. A p-value ≤0.05 was considered statistically significant. Ethical approval for the study was obtained from the hospital's institutional review board (IRB). All study procedures adhered to the ethical standards outlined in the Declaration of Helsinki, ensuring participant confidentiality and voluntary participation.

RESULTS

The study included a total of 110 children with iron deficiency anemia, equally distributed between the sucrose and polymaltose groups (n=55 each). The mean age of participants in the sucrose group was 3.11 ± 1.37 years, while those in the polymaltose group had a mean age of 3.73 ± 1.46 years. Children aged three years or younger comprised 53.4% of the sucrose group and 46.6% of the polymaltose group. The gender distribution was nearly even, with males accounting for 60% of the total sample; specifically, 33 males (48.5%) were in the sucrose group and 35 (51.5%) in the polymaltose group. Vaccination coverage varied slightly between groups, with 19 vaccinated children (44.2%) in the sucrose group compared to 24 (55.8%) in the polymaltose group. Regarding family history of anemia, a higher proportion was reported in the sucrose group (72.4%) compared to the polymaltose group (27.6%). Rural residence was more common in both groups, with 29 children (46.8%) from rural areas in the sucrose group and 33 (53.2%) in the polymaltose group. Maternal education showed some disparity, with no formal education reported in 17 mothers (73.9%) in the sucrose group versus 6 (26.1%) in the polymaltose group. A higher number of mothers in the polymaltose group had education at matric level or above.

The mean baseline hemoglobin was 7.64 ± 2.60 g/dl in the sucrose group and 8.00 ± 2.37 g/dl in the polymaltose group. Following treatment, mean post-treatment hemoglobin levels rose to 9.89 ± 1.61 g/dl in the sucrose group and 9.63 ± 1.94 g/dl in the polymaltose group. However, the difference in post-treatment hemoglobin levels between the groups was not statistically significant (p = 0.457). In terms of treatment efficacy—defined as an increase in hemoglobin of at least 2 g/dl—38 children (57.6%) in the sucrose group met the criteria, compared to 28 (42.4%) in the polymaltose group. Although this suggests a higher efficacy rate in the sucrose group, the difference approached but did not reach statistical significance (p = 0.052). The mean increase in hemoglobin level from baseline to post-treatment was found to be 2.25 g/dl in the sucrose group and 1.63 g/dl in the polymaltose group. This difference was statistically significant, with a p-value of 0.011, indicating that children treated with intravenous iron sucrose experienced a greater improvement in hemoglobin levels compared to those who received oral iron polymaltose complex. This finding aligns with the observed trend in efficacy rates and further reinforces the superior performance of iron sucrose in increasing hemoglobin concentration in pediatric patients with iron deficiency anemia.

Table 1: Baseline characteristics of study participants (n = 110, 55 in each group)

		Group		Total
		Sucrose (n =55)	Polymaltose (n =55)	
Age (years)	3 and below	31	27	58
		53.4%	46.6%	100.0%
	More than 3	24	28	52
		46.2%	53.8%	100.0%
Gender	Male	33	35	68
		48.5%	51.5%	100.0%
	Female	22	20	42
		52.4%	47.6%	100.0%
Vaccination	Yes	19	24	43

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		Group		Total
		Sucrose (n =55)	Polymaltose (n =55)	
		44.2%	55.8%	100.0%
	No	36	31	67
		53.7%	46.3%	100.0%
Family Hx	Yes	21	8	29
		72.4%	27.6%	100.0%
	No	34	47	81
		42.0%	58.0%	100.0%
Residence	Rural	29	33	62
		46.8%	53.2%	100.0%
	Urban	26	22	48
		54.2%	45.8%	100.0%
Education of mother	No formal schooling	17	6	23
		73.9%	26.1%	100.0%
	Matric or below	25	31	56
		44.6%	55.4%	100.0%
	Above matric	13	18	31
		41.9%	58.1%	100.0%

Table 2: Comparison of efficacy in sucrose versus polymaltose group (n = 110, 55 in each group)

		Group		Total	P value
		Sucrose (n =55)	Polymaltose (n = 55)		
Efficacy	Yes	38	28	66	0.052
		57.6%	42.4%	100.0%	
	No	17	27	44	
		38.6%	61.4%	100.0%	
Total		55	55	110	
		50.0%	50.0%	100.0%	

Table 3: Comparison of mean difference in hemoglobin level in sucrose versus polymaltose group (n =110, 55 in each group)

	Group	N	Mean	Std. Deviation	Std. Error Mean	p value
Hb (gm/dl)	Sucrose	55	9.8909	1.61787	.21815	0.457
	Polymaltose	55	9.6364	1.94711	.26255	

Table 4: Mean Hemoglobin Increase Comparison

Group	Mean Increase in Hb (g/dl)	n
Sucrose	2.25	55
Polymaltose	1.63	55

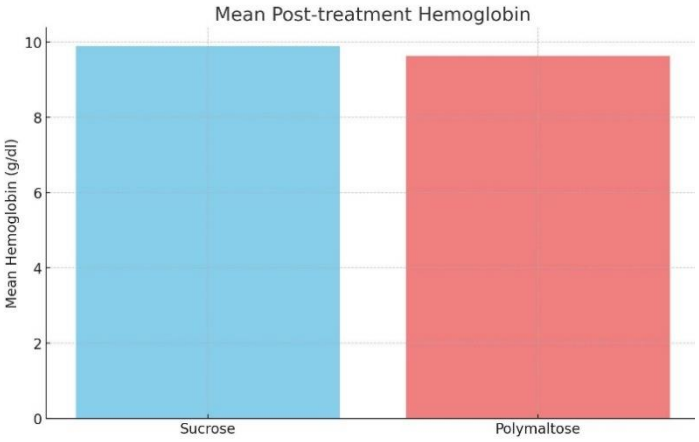

Figure 1 Mean Post-treatment Hemoglobin

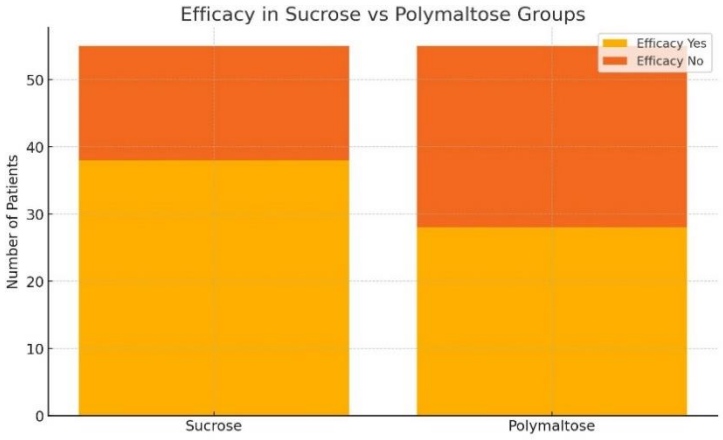

Figure 2 Efficacy in Sucrose vs Polymaltose Groups

DISCUSSION

Iron deficiency anemia (IDA) remains a significant global health concern, affecting over 30% of the world's population, with a disproportionately higher burden among infants and young children (11). In Pakistan, IDA constitutes approximately 65% of all anemia cases and is predominantly attributed to nutritional deficiencies (12,13). The condition is influenced by a range of socioeconomic and demographic factors including maternal education, parenting practices, income level, and number of children in a household (14). In early childhood, risk factors such as preterm birth, delayed introduction of solid foods, prolonged consumption of unfortified cow's milk, and gastrointestinal conditions including celiac disease and worm infestation are known contributors to iron depletion (15). Clinically, IDA in children is often manifested by symptoms such as pallor, reduced appetite, cognitive delays, and behavioral changes including irritability and impaired concentration (16). Findings from the present study demonstrated that intravenous iron sucrose led to a greater mean increase in hemoglobin compared to oral iron polymaltose complex in children aged 6 months to 5 years diagnosed with IDA. Although the difference in efficacy did not achieve statistical significance in binary terms ($p = 0.052$), the mean rise in hemoglobin was significantly higher in the intravenous group (2.25 g/dl vs. 1.63 g/dl, $p = 0.011$), suggesting a superior clinical response. These results are in line with regional studies indicating faster and more effective hemoglobin recovery with parenteral iron therapy in both pediatric and obstetric populations (17,18). The higher bioavailability and bypassing of intestinal absorption issues likely contribute to the enhanced performance of intravenous formulations.

Some research in children has emphasized that injectable iron regimens not only reduce gastrointestinal side effects but also improve treatment adherence and reduce the frequency of hospital admissions when administered in a controlled outpatient setting. Enhanced erythropoietic response observed in such patients may stem from better compliance and fewer gastrointestinal losses compared to oral formulations. While the present study supports these observations, it also highlights the logistical challenges associated with intravenous iron administration, such as the need for monitored settings and the rare but potential risk of hypersensitivity reactions (19,20). This study's strength lies in its randomized controlled design, equal sample allocation, and direct comparison of two widely used iron preparations in a pediatric cohort. It is also among the limited body of clinical investigations to evaluate these specific formulations head-to-head in young children. However, the study faced limitations including a relatively small sample size, short follow-up duration, and reliance on hemoglobin as the sole biomarker of treatment response. The absence of ferritin or transferrin saturation follow-up post-treatment limits the comprehensive assessment of iron store replenishment. Furthermore, the exclusion of children with chronic gastrointestinal conditions and the single-center design may limit the generalizability of findings.

The observed improvement in hemoglobin in both treatment arms confirms that iron replacement remains effective in managing pediatric IDA, but the choice of formulation should balance efficacy, safety, accessibility, and caregiver compliance. Intravenous iron therapy may offer a viable alternative for patients with poor response or intolerance to oral regimens, provided that administration infrastructure is available. Future studies with larger, multicentric designs, longer follow-up periods, and inclusion of iron indices such as serum ferritin

and transferring saturation would help validate and extend these findings. Incorporating cost-effectiveness analysis and assessing quality-of-life outcomes may also offer a more holistic evaluation of treatment strategies for childhood IDA.

CONCLUSION

This study concludes that both iron sucrose and iron polymaltose complex are effective options for treating iron deficiency anemia in children. While iron sucrose showed a marginal advantage in improving hemoglobin levels, the difference was not statistically significant. Therefore, when selecting a treatment approach, practical considerations such as patient adherence, affordability, and ease of administration should guide clinical decisions. These findings support a flexible, patient-centered strategy in managing pediatric iron deficiency anemia.

AUTHOR CONTRIBUTION

Author	Contribution
Abdur Rahman	Substantial Contribution to study design, analysis, acquisition of Data Manuscript Writing Has given Final Approval of the version to be published
Jan Mohammad	Substantial Contribution to study design, acquisition and interpretation of Data Critical Review and Manuscript Writing Has given Final Approval of the version to be published
Sajid Hussain	Substantial Contribution to acquisition and interpretation of Data Has given Final Approval of the version to be published
Momina Waheed*	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published
Nayab E Alam	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published
Zeeshan Ahmad	Substantial Contribution to study design and Data Analysis Has given Final Approval of the version to be published
Madiha Gul	Contributed to study concept and Data collection Has given Final Approval of the version to be published
Saphia E Alam	Writing - Review & Editing, Assistance with Data Curation

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